

Michael J. Friedman (MF-0251)
WINSTON & STRAWN LLP
200 Park Avenue
New York, New York
Tel: (212) 294-6700
Fax: (212) 294-4700
mfriedman@winston.com

Counsel for Abbott Laboratories

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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: 1:07-CV-05634-AKH-DFE
DR. ANTHONY CERAMI, :
:
Plaintiff, :
:
- against - :
:
NOVARTIS AG and NOVARTIS VACCINES :
AND DIAGNOSTICS, INC., :
:
Defendant. :
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**REPLY MEMORANDUM OF LAW IN SUPPORT OF ABBOTT
LABORATORIES' MOTION TO INTERVENE FOR THE LIMITED
PURPOSE OF REQUESTING A PROTECTIVE ORDER**

PROCEDURAL UPDATE

Proposed intervenor Abbott Laboratories ("Abbott") filed this motion in order to protect from disclosure in this action certain highly sensitive, confidential information (the "TNF Litigation Documents") that is already in Defendant Novartis's custody as the result of an earlier patent litigation between Abbott and Novartis (the "TNF litigation").

The information Abbott seeks to protect is extraordinarily valuable, constituting proprietary and trade secret information underlying Abbott's HUMIRA biologic product. HUMIRA is one of the fastest growing biologics on the market today and is one of Abbott's flagship products. U.S. sales of HUMIRA in the nine month period ending September 30, 2007 were about \$1.1 billion. Disclosure of the confidential TNF Litigation Documents would cause Abbott to suffer economic harm.

At the time Abbott filed this motion there was no protective order in place in this action, and Novartis had indicated in its initial disclosures its intent to produce (a) settlement-related documents from the TNF litigation, and (b) certain documents from the TNF litigation that are currently subject to the protective order entered therein. Since then, Novartis and Dr. Cerami have agreed to the terms of a Stipulated Protective Order (the "Protective Order") that Abbott agrees will adequately protect its interests in maintaining the confidentiality of settlement-related documents. Also since the time Abbott filed this motion, Novartis has indicated that the "certain documents from the TNF litigation" referred to in Novartis's initial disclosures, were limited to the transcript of Dr. Cerami's deposition in the TNF litigation, a document already in Dr. Cerami's possession. Thus, the immediate threatened disclosures that prompted Abbott's motion have been adequately addressed by the parties.

However, Novartis still maintains possession of extremely sensitive confidential information produced in the TNF litigation, and Abbott still maintains a strong interest in

obtaining protections that will adequately protect that information. Abbott's continued concern that this information may yet be disclosed is evidenced by Novartis's position that it may elect to amend its Rule 26(a) disclosures to include other documents from the TNF Litigation.

In recognition of the above progression of events, on December 14th Abbott proposed to the parties the following addition to the Protective Order, offering to withdraw this motion if both Novartis and Dr. Cerami agree to it:

Any party intending to produce materials designated as "CONFIDENTIAL" by Abbott pursuant to the protective order in the Patent Litigation shall provide written notice of its intent to do so to Abbott, including a description of the materials the party intends to produce, and shall not produce any such materials until the later of (a) 14 days after such written notice to Abbott, or (b) this Court's ruling on any motion for a protective order filed by Abbott within 14 days after such written notice.

As of the date of this filing, neither Novartis nor Dr. Cerami has taken a position as to whether this addition is acceptable. If Abbott's proposal is adopted, this motion will be withdrawn.

If it is not, Abbott has standing to intervene and still has met its burden to obtain a protective order. First, as the only party with an interest in maintaining the threatened confidentiality, it is clear that Abbott has standing to request a protective order. Second, as part of its proper effort to seek a protective order, Abbott certainly has standing to present arguments about the irrelevance of the information at issue to any claim or defense in the current action. Abbott's arguments on that point are, in fact, a critical element of the balancing test that demonstrates the level of high level of protection necessary. Dr. Cerami has cited no authority to the contrary, but instead relies on inapposite cases that have no factual similarity to Abbott's pending motion. Finally, Abbott has shown not only that Dr. Cerami's request for sanctions is procedurally inappropriate, but also that it has no merit, particularly in view of Abbott's continued good faith efforts to resolve this dispute privately. Abbott's motion to intervene and

for a protective order should therefore be granted, and Dr. Cerami's inappropriate request for sanctions should be denied and disregarded.

ARGUMENT

I. ABBOTT HAS STANDING TO ASSERT THAT THE TNF LITIGATION DOCUMENTS ARE IRRELEVANT, CONFIDENTIAL, AND DESERVING OF PROTECTION FROM DISCLOSURE IN THIS CASE.

Federal Rule 26(c)(1) allows this Court to order that Abbott's confidential and irrelevant information not be produced in this action. Courts conduct a three-part analysis when determining whether to issue a protective order under Rule 26(c). "First, the party resisting discovery has the burden of showing that the information requested is confidential and its disclosure would be harmful. Then the burden shifts to the party seeking discovery to demonstrate that the information sought is relevant and necessary. Finally, the court must weigh the need for the information against the harm that would result from disclosure." *Madanes v. Madanes*, 186 F.R.D. 279, 288 (S.D.N.Y. 1999); *see also Burns v. Bank of Am.*, No. 03-1685, 2007 U.S. Dist. LEXIS 40037, at *51 (S.D.N.Y. June 4, 2007); *MacWade v. Kelly*, 230 F.R.D. 379, 382-83 (S.D.N.Y. 2005) ("Simply put, there does not at this time appear to be a 'substantial need' for disclosure of the disputed material.").

A. ABBOTT HAS STANDING TO ASSERT THAT THE TNF LITIGATION DOCUMENTS ARE CONFIDENTIAL, AND HAS MADE THAT SHOWING.

As to the first prong of this analysis, the law in this Circuit is clear that "a motion for a protective order pursuant to Rule 26(c) 'must be brought by the individual whose interests are affected....' *Am. Rock Salt Co., LLC v. Norfolk S. Corp.*, 228 F.R.D. 426, 466 (W.D.N.Y. 2005). Further, although "a party may not move for a protective order to protect the interests of another, [it] may move to protect the party's *own* interests when discovery is sought from another." *Id.* (emphasis added). That is exactly the situation Abbott faces here. As the

entity whose confidential information is at risk, Abbott must be able to demonstrate the harm that would result from disclosure and seek a protective order to shield that information.

As set forth in Abbott's opening memorandum and supported by the Affidavit of Scott Luce attached hereto as Exhibit A, Abbott has unquestionably met its "burden of showing that the information requested is confidential and its disclosure would be harmful." *Madanes*, 186 F.R.D. at 288. The HUMIRA product to which the confidential TNF Litigation Documents relate currently generates in excess of \$2 billion per year in sales. (Exhibit A, ¶ 7.) Abbott views certain information about the research and development underlying HUMIRA, the composition of HUMIRA and the sales and marketing strategies regarding HUMIRA to be highly confidential, trade secret information. (*Id.* ¶ 8.) Abbott was required to produce a significant amount of this highly confidential, trade secret information in the TNF litigation. (*Id.* ¶ 9.) Mr. Luce states that "further disclosure of that information could assist Abbott's competitors to amend or modify current research and development programs, or to alter current sales and marketing strategies for competing products, in order to more effectively compete with HUMIRA. It would also provide competitors with confidential information that would assist them in crafting future patent strategies." (*Id.* ¶ 12.) The result of such disclosure would be a "weakened competitive position and could result in losses in the millions of dollars for Abbott, based on the result of future patent disputes and market position relative to Abbott's competitors." (*Id.* ¶ 13.) Dr. Cerami has no evidence in response to the argument that disclosure of this confidential information would be harmful to Abbott.

B. ABBOTT HAS STANDING TO ASSERT THAT THE TNF LITIGATION DOCUMENTS ARE IRRELEVANT.

As part of its showing that a protective order is necessary, Abbott also has standing to assert that the TNF Litigation Documents are irrelevant. "Rule 26(b) of the Federal

Rules of Civil Procedure limits discovery to relevant matters, and makes no distinction in this regard between information in the hands of parties and that held by nonparties.” *Fein v. Numex Corp.*, 92 F.R.D. 94, 96 (S.D.N.Y. 1981). Indeed, “it is difficult to imagine a considered evaluation of burdensomeness . . . without balancing the degree of burdensomeness against the extent to which the discovery sought is relevant to the issues in the litigation.” *Id.* (holding that nonparty accounting firm served with subpoena had standing to object to the relevance of documents sought); *see also Fort James Corp. v. Sweetheart Cup Co., Inc.*, No. 97-1221, 1998 U.S. Dist. LEXIS 15908, at *5 (S.D.N.Y. Oct. 8, 1998) (quashing subpoena and noting that a protective order is not “a substitute for a showing of relevance”). That Abbott is a non-party to this action does not mean that any party can simply “romp through the files of basically unrelated, competitive entities without making the necessary showing of relevance.” *Id.*

Dr. Cerami has not cited any cases that support his incorrect notion that a third-party has no standing to raise questions of relevance with respect to discovery materials. Instead, he is left quoting language to the effect that “[s]ome federal courts are *reluctant* to address the objection of a non-party to a discovery request *solely* on grounds of relevance,” and that some courts have “reservations” about a non-party asserting irrelevance. *Goland v. Iglesias*, No. 85-9697, 1988 U.S. Dist. LEXIS 3528, at *56 (S.D.N.Y. April 21, 1988) (emphasis added); *Ghandi v. Police Dept. of the City of Detroit*, 74 F.R.D. 115, 123 (E.D. Mich. 1977). Yet in none of the cases Dr. Cerami cites does the court hold that a third-party has no standing to question relevance, and in none of those cases does the court proceed without addressing the relevance question.

Not only does Abbott have standing to argue that the TNF Litigation Documents are irrelevant, but cases within the Second Circuit demonstrate that Abbott has used the accepted

and appropriate procedure for doing so. *See AT&T Corp. v. Sprint Corp.*, 407 F.3d 560, 561-62 (2d Cir. 2005) (stating “that permissive intervention is the proper method for a nonparty to seek a modification of a protective order,” where non-party sought intervention to gain access to documents covered by protective order); *Schiller v. The City of New York*, 04-7922, 2006 U.S. Dist. LEXIS 70479, at *5 (S.D.N.Y. Sept. 27, 2006) (granting permissive intervention to New York Times and unsealing documents). As Abbott has standing and has employed this accepted procedure, it may argue in support of its motion for a protective order that the materials are irrelevant, so that the Court may properly balance competing interests. *Martindell v. Int'l Tel. & Tel. Corp.*, 594 F.2d 291, 294 (2d Cir. 1979) (explaining that as the government was not a party to the litigation, it could not merely insinuate itself in discovery matters, because “[t]he proper procedure, as the Government should know, was . . . to seek permissive intervention in the private action pursuant to Rule 24(b), F.R.Civ.P., for the purpose of obtaining vacation or modification of the protective order”); *see also Cole Mech. Corp. v. Nat’l Grange Mut. Ins. Co.*, No. 06-2875, 2007 U.S. Dist. LEXIS 66584, at *9 (S.D.N.Y. Sept. 7, 2007) (granting non-party corporation's motion to intervene and for a protective order staying discovery); *Torah Soft Ltd. v. Drosnin*, No. 00-0676, 2001 U.S. Dist. LEXIS 18614, at *5-*6 (S.D.N.Y. Nov. 14, 2001) (granting non-party John Doe's motion to intervene to seek a protective order and considering Doe's argument that documents were irrelevant); *Blum v. Schlegel*, 150 F.R.D. 38, 39 (W.D.N.Y. 1993) (granting motion to intervene and granting protective order prohibiting production of personnel files that were irrelevant to claims at issue).

1. THE TNF LITIGATION DOCUMENTS ARE IRRELEVANT TO THIS CASE

The parties may now agree that the TNF Litigation Documents are irrelevant to this case. Since the time of the filing of this motion, Novartis has taken the position that it does

not presently intend to produce any TNF Litigation Documents, and Dr. Cerami has not yet challenged that position. Accordingly, Abbott requested that the parties approve an addition to their Protective Order that would permit Abbott and the parties to defer any dispute over production of TNF Litigation Documents and their relevance to this case until such time as Novartis plans to produce a particular TNF Litigation Document.

That said, it is difficult to fathom how confidential information about the intellectual property involved in Abbott's HUMIRA product could have any relevance to this dispute over the breach of a 1985 contract. Novartis's claims against Abbott have already been resolved in the TNF Litigation and are now a closed book. There is no reason for Dr. Cerami to reopen that book in determining his rights against Novartis.

Moreover, Dr. Cerami has not made any showing that the TNF Litigation Documents are "necessary or relevant" to its claims. The single fact he cites is Novartis's listing of certain documents in its initial disclosures. (Pltf.'s Resp. Br., at 7-8.) As discussed above, however, Novartis has since represented that the only document it was referring to was Dr. Cerami's deposition transcript – a document that contains no Abbott-confidential information and that Dr. Cerami already has.

Given the strong showing of Abbott's confidentiality interest in the TNF Litigation Documents and Cerami's inability to demonstrate the relevance of those documents to the case at hand, Abbott's interests in maintaining confidentiality clearly outweigh any demonstrated need for the those materials. Abbott therefore respectfully requests that this Court enter a protective order under Fed. R. Civ. P. 26(c)(1) requiring the complete nondisclosure of the TNF Litigation Documents. In the event that this Court finds that complete nondisclosure of

the TNF Litigation Documents is not appropriate, Abbott requests that this Court enter the requested modification in the Protective Order agreed to by Dr. Cerami and Novartis.

II. THIS COURT SHOULD NOT IMPOSE SANCTIONS AGAINST ABBOTT AS DR. CERAMI FAILED TO USE THE MANDATORY SAFE HARBOR PROVISION OF RULE 11, AND ABBOTT HAS HAD AN ADEQUATE BASIS IN LAW AND FACT FOR EACH POSITION TAKEN IN THIS MATTER.

Rule 11 “requires a party seeking to bring a motion for sanctions to do so by a motion ‘made separately from other motions or requests,’ and only after having first served its adversary with the motion at least twenty-one days before filing the motion with the Court.” *Carofino v. Forester*, 450 F. Supp. 2d 257, 274 (S.D.N.Y. 2006) (quoting Fed. R. Civ. P. 11(c)(1)(A)). The safe harbor provisions of Rule 11 exist in order to prevent a party from calling his adversary's professionalism into question before the Court until after his adversary has had the opportunity to reevaluate and/or withdraw its position. Dr. Cerami's accusations before this Court were included in his opposition to Abbott's motion to intervene and predate his service of any Rule 11 motion, therefore violating that Rule's safe harbor provisions.

“In this Circuit, compliance with the procedural requirements of Rule 11 is mandatory. Sanctions may not be imposed if the party seeking them failed to comply with the technical requirements of Rule 11.” *Carruthers v. Flaum*, 450 F. Supp. 2d 288, 304 (S.D.N.Y. 2006); *see also Estate of Davis v. Trojer*, 287 F. Supp. 2d 455, 457 (S.D.N.Y. 2003) (sanctioning defendant under Rule 11 for asserting Rule 11 violation against plaintiff without complying with safe harbor provisions).

“The Court need not reach the flimsiness of [Cerami's] substantive argument because [it has] failed to comply with the Rule 11 procedural requirements.” *Carofino*, 450 F. Supp. 2d at 274. However, even if the Court decides to entertain Cerami's motion for sanctions, the motion should be denied on the merits. Abbott was faced with the imminent disclosure of its

confidential information, undertook to determine the proper procedure for a non-party to obtain a protective order, and filed its motion to intervene for the limited purpose of requesting a protective order in good faith and in accordance with the accepted procedures of courts in this Circuit. Moreover, Abbott has continually offered to negotiate with Dr. Cerami and continually offered to extend the deadline for any response to Abbott's motion while the parties appeared to be making progress toward a private resolution to this dispute. That is evidence only of good faith, and certainly not of vexatious litigation tactics that Dr. Cerami accuses Abbott of employing.

This Court must deny Cerami's request for sanctions because he has failed to make his request in a separate motion and failed to comply with the mandatory safe harbor provision of the Rule. Furthermore, Abbott has an adequate basis in fact and in law for every position it has taken in its efforts to obtain a protective order. Sanctions are therefore entirely unwarranted.

CONCLUSION

For the reasons stated above, Abbott respectfully requests that this Court grant Abbott's Motion to Intervene in its entirety and enter a protective order prohibiting the disclosure of the TNF Litigation Documents, containing Abbott-confidential information, produced during pretrial discovery in *The Rockefeller University and Chiron Corporation v. Centocor Inc. and Abbott Laboratories*, Civil Action No. 2-04CV-168-TJW. Alternatively, Abbott requests that this Court enter the proposed additions to the Stipulated Protective Order agreed upon by Cerami and Novartis.

Dated: December 17, 2007
New York, New York

WINSTON & STRAWN LLP

By: /s/ Michael J. Friedman

Michael J. Friedman
200 Park Avenue
New York, New York
Tel: (212) 294-6700
Fax: (212) 294-4700
mfriedman@winston.com

Counsel for Abbott Laboratories